Regulation 1591

Medicines and Medical Devices (Ear Implant Devices)

Complete Rule Making File

OAL Approval

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State of California
Office of Administrative Law

In re:	**NOTICE OF APPROVAL OF REGULATORY ACTION**
Board of Equalization	
Regulatory Action:	**Government Code Section 11349.3**
Title 18, California Code of Regulations	**OAL File No. 2009-0319-01 S**
Adopt sections: **Amend sections: 1591** **Repeal sections:**	

This action amends existing provisions governing the application of sales and use tax to "Medicines or Medical Devices" by clarifying that no tax applies to any "permanently implantable articles" including an implant's interdependent internal and external components which operate together as one device in and on the person in whom the device is implanted, unless such device is specifically excluded from the definition of "medicines".

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 5/29/2009.

Date: 4/29/2009

Gordon R. Young
Senior Staff Counsel

For: SUSAN LAPSLEY
Director

Original: Ramon Hirsig
Copy: Richard Bennion

OFFICE OF ADMINISTRATIVE LAW
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SUSAN LAPSLEY
Director

MEMORANDUM

TO: Richard Bennion
FROM: OAL Front Desk
DATE: 4/30/2009
RE: Return of Approved Rulemaking Materials
OAL File No. 2009-0319-01S

OAL hereby returns this file your agency submitted for our review (OAL File No. 2009-0319-01S regarding Medicines and Medical Devices).

If this is an approved file, it contains a copy of the regulation(s) stamped "ENDORSED APPROVED" by the Office of Administrative Law and "ENDORSED FILED" by the Secretary of State. The effective date of an approved file is specified on the Form 400 (see item B.5). (Please Note: The 30th Day after filing with the Secretary of State is calculated from the date the Form 400 was stamped "ENDORSED FILED" by the Secretary of State.)

DO NOT DISCARD OR DESTROY THIS FILE

Due to its legal significance, you are required by law to preserve this rulemaking record. Government Code section 11347.3(d) requires that this record be available to the public and to the courts for possible later review. Government Code section 11347.3(e) further provides that "....no item contained in the file shall be removed, altered, or destroyed or otherwise disposed of." See also the Records Management Act (Government Code section 14740 et seq.) and the State Administrative Manual (SAM) section 1600 et seq.) regarding retention of your records.

If you decide not to keep the rulemaking records at your agency/office or at the State Records Center, you may transmit it to the State Archives with instructions that the Secretary of State shall not remove, alter, or destroy or otherwise dispose of any item contained in the file. See Government Code section 11347.3(f).

Enclosures

STATE OF CALIFORNIA—OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION/REGULATIONS SUBMISSION

REGULAR

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STD. 400 (REV. 01-09)

For use by Secretary of State only

ENDORSED FILED IN THE OFFICE OF

2009 APR 29 PM 1:37

Debra Bowen

DEBRA BOWEN
SECRETARY OF STATE

OAL FILE NUMBERS	NOTICE FILE NUMBER	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
	Z-08190201	2009-0319-01S	

For use by Office of Administrative Law (OAL) only

2009 MAR 19 PM 1:02

OFFICE OF ADMINISTRATIVE LAW

NOTICE | REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY
State Board of Equalization

AGENCY FILE NUMBER (If any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE

3. NOTICE TYPE	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
☐ Notice re Proposed Regulatory Action ☐ Other			

OAL USE ONLY	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE
	☐ Approved as Submitted ☐ Approved as Modified ☐ Disapproved/ Withdrawn	08-#50-Z	12-12-2008

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S)	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
Medicines and Medical Devices	

SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) **(Including title 26, if toxics related)**

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT	
	AMEND	1591
TITLE(S) 18	REPEAL	

3. TYPE OF FILING

- ☒ Regular Rulemaking (Gov. Code §11346)
- ☐ Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)
- ☐ Emergency (Gov. Code, §11346.1(b))
- ☐ Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
- ☐ Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
- ☐ Emergency Readopt (Gov. Code, §11346.1(h))
- ☐ File & Print
- ☐ Other (Specify) _____
- ☐ Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
- ☐ Print Only

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

- ☒ Effective 30th day after filing with Secretary of State
- ☐ Effective on filing with Secretary of State
- ☐ §100 Changes Without Regulatory Effect
- ☐ Effective other (Specify) _____

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

- ☐ Department of Finance (Form STD. 399) (SAM §6660)
- ☐ Fair Political Practices Commission
- ☐ State Fire Marshal
- ☐ Other (Specify) _____

7. CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional)
Richard E. Bennion	(916) 445-2130	(916) 324-3984	rbennion@boe.ca.gov

8. **I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.**

SIGNATURE OF AGENCY HEAD OR DESIGNEE	DATE
Diane G. Olson	3/19/09

TYPED NAME AND TITLE OF SIGNATORY
Diane G. Olson, Chief, Board Proceedings Division

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

APR 29 2009

Office of Administrative Law

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility.A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and

IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be

individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed

physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIETARY SUPPLEMENTS AND ADJUNCTS. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

NOTE: Authority cited: Section 7051, Revenue and Taxation Code.
Reference: Sections 6006 and 6369, Revenue and Taxation Code; and sections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.

4/29/09

3. Proposed Regulation is Not a Standard of General Application

The proposed regulation does not establish any standard that implements, interprets, or makes specific the law enforced by the Board. It only establishes an enforcement policy for the Board's staff to focus on the adequacy of the audits regarding verification of assets invested in the "Madoff-type scheme." Although the petitioner provides several examples of consumer harm from the "Madoff investment Ponzi scheme," no evidence or documentation is provided showing other examples of any other "Madoff-type schemes" involving California licensees. It appears as though this proposed regulation is specifically directed at the Madoff investment Ponzi scheme and the licensed accountants who were involved in that scheme. The proposed regulation does not appear to be standard of general application.

DECISION

For all the reasons stated above, the rulemaking petition submitted by Mr. Carl Olson is hereby denied.

PATTI BOWERS
Executive Officer
California Board of Accountancy

cc: Carl Olson

DECLARATION OF PERSONAL SERVICE

I, Gary W. Duke, say and declare:

That I am a citizen of the United States over the age of eighteen years; that on the 5th day of May 5, 2009, I personally served the attached

Notice of Decision on Petition to Adopt a Regulation
to
California Office of Administrative Law

at 300 Capitol Mall, Suite 1250, Sacramento in the County of Sacramento, State of California, by then and there delivering to and leaving with said California Office of Administrative Law a true copy thereof.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on May 5, 2009 at Sacramento, California.

/s/
Gary W. Duke

DECISION NOT TO PROCEED

TITLE 22. EMERGENCY MEDICAL SERVICES AUTHORITY

NOTICE OF DECISION NOT TO PROCEED

Pursuant to Government Code Section 11347, the Emergency Medical Services Authority hereby gives notice that it has decided not to proceed with Emergency Medical Technician-II Regulations, Chapter 3, Division 9 of Title 22, (Notice File No. Z2008-0617-02) as published in the California Regulatory Notice Register on June 27, 2008.

Any interested person with questions concerning this rulemaking should contact Laura Little at (916) 322-4336 or by e-mail at: Laura.Little@emsa.ca.gov.

SUMMARY OF REGULATORY ACTIONS

REGULATIONS FILED WITH SECRETARY OF STATE

This Summary of Regulatory Actions lists regulations filed with the Secretary of State on the dates indicated. Copies of the regulations may be obtained by contacting the agency or from the Secretary of State, Archives, 1020 O Street, Sacramento, CA 95814, (916) 653-7715. Please have the agency name and the date filed (see below) when making a request.

File# 2009-0319-01
BOARD OF EQUALIZATION
Medicines and Medical Devices

This action amends existing provisions governing the application of sales and use tax to "Medicines or Medical Devices" by clarifying that no tax applies to any "permanently implantable articles" including an implant's interdependent internal and external components which operate together as one device in and on the person in whom the device is implanted, unless such device is specifically excluded from the definition of "medicines".

Title 18
California Code of Regulations
AMEND: 1591
Filed 04/29/2009
Effective 05/29/2009
Agency Contact:
Richard Bennion (916) 445-2130

Rulemaking File Index

Title 18. Public Revenue

Sales and Use Tax

Regulation 1591, Medicines and Medical Devices (Ear Implant Devices)

1. *Final Statement of Reasons*
2. *Updated Informative Digest*
3. *Business Tax Committee Minutes,*

    - Minutes
    - Text of Proposed regulation
    - Formal Issue Paper Number 08-012
    - Regulation History

4. *Reporter's Transcript Business Taxes Committee, November 12, 2008*
5. *Estimate of Cost or Savings, November 26, 2008*
6. *Economic and Fiscal Impact Statements, November 26, 2008*
7. *Notice of Publications*

    - Form 400 and notice, December 2, 2008
    - Notice of Hearing
    - Proposed Text of Regulations 1591
    - Email sent to Interested Parties, December 12, 2008
    - CA Regulatory Notice Register 2008, Volume No. 50-Z

8. *Notice to Interested Parties, December 12, 2008*

    The following items are exhibited:

    - Interested Parties Notice of Hearing
    - Initial Statement of Reasons
    - Proposed Text of Regulations 1591
    - Regulation History

9. *Statement of Compliance*
10. *Reporter's Transcript, Item F2, Public Hearing, February 3, 2009*
11. *Minutes, February 3, 2009, and Exhibits*

The following items are exhibited:

- Notice of Proposed Regulatory Action
- Initial Statement of Reasons
- Proposed Text of Regulations 1591
- Regulation History

VERIFICATION

I, Richard E. Bennion, Regulations Coordinator of the State Board of Equalization, state that the rulemaking file of which the contents as listed in the index is complete, and that the record was closed on March 12, 2009 and that the attached copy is complete.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

March 12, 2009

Richard E. Bennion
Regulations Coordinator
State Board of Equalization

Title 18, Public Revenue

Sales and Use Tax Regulation 1591, Medicines and Medical Devices

FINAL STATEMENT OF REASONS
Overview/Non-Controlling Summary

Update

There have been no changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Regulatory Action.

Specific Purpose

The purpose of the proposed amendments to California Code of Regulations, title 18, sections 1591, *Medicines and Medical Devices*, is to amend, subdivision (b)(2), to clarify that tax does not apply to the sale of *all* "permanently implanted articles" including an implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

Necessity

This regulation is necessary to provide clarification to taxpayers and staff regarding the taxation of implanted medical devices.

Factual Basis

On February 27, 2008, the Board of Equalization (Board) heard a sales and use tax appeals case regarding the sales of cochlear implant devices. At issue was whether sales of the external components of the ear implant device qualified for exemption from tax in the same manner as the permanently implanted internal components. The petitioner explained that the internal and external components of the ear implant device are effectively one device, with each component mutually dependent on the other to function. Together, the internal and external components of the ear implant device assist in the functioning of the ear, each necessary and integral to the ongoing function of the ear and, as such, both qualify as "medicines". The Board agreed with the petitioner and instructed staff to amend Regulation 1591 to clarify the matter.

Local Mandate Determination

The Board has determined that the proposed amendments do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to ay State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

Response to Public Comment

On November 3, 2009, the Board held a public hearing on the proposed amendments to Sales and Use Tax Regulation 1591. No public comment was received at the hearing or during the public comment period.

Small Business Impact

The State Board of Equalization has determined that the adoption of the amendments to Regulation 1591 will have no significant statewide adverse economic impact directly affecting small business. The adoption of the proposed amendments to this regulation will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California. The amendments to the regulation as proposed will not be detrimental to California business in competing with businesses in other states. The proposed regulation may affect small business.

Cost Impact on Private Person or Businesses

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Significant Effect on Housing Costs

No significant effect.

Federal Regulations

Regulation 1591 and the proposed changes have no comparable federal regulations.

Alternatives Considered

By its motion, the Board determined no alternative to promulgating the regulations would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective as and less burdensome to affected private persons than the adopted regulation.

Authority

Section 7051, Revenue and Taxation Code

Reference

Reference: Section 6369, Revenue and Taxation Code

Title 18. Public Revenue

Sales and Use Tax Regulation 1591, Medicines and Medical Devices

UPDATED INFORMATIVE DIGEST

There have been no changes in applicable laws or to the effect of the proposed regulation from the laws and effects described in the Notice of Proposed Regulatory Action.

BOARD OF EQUALIZATION
BUSINESS TAXES COMMITTEE MEETING MINUTES

HONORABLE BETTY T. YEE, COMMITTEE CHAIR
450 N STREET, SACRAMENTO
MEETING DATE: NOVEMBER 12, 2008, TIME: 9:30 A.M.

ACTION ITEMS & STATUS REPORT ITEMS

Agenda Item No: 1

Title: Proposed regulatory changes regarding ear implants

Issue/Topic:

Should Regulation 1591, *Medicines and Medical Devices*, be amended to clarify the application of tax to sales of ear implant devices with their mutually dependent internal and external components?

Committee Discussion:

The Board Members discussed the two alternative proposals to clarify the application of tax to sales of the interdependent internal and external components of a permanently implanted article.

Committee Action/Recommendation/Direction:

Upon motion by Ms. Yee, seconded by Dr. Chu, the Committee unanimously approved and authorized for publication the proposed amendments to Regulation 1591, *Medicines and Medical Devices,* contained in Alternative 2. There is no operative date, and implementation will take place 30 days after approval by the Office of Administrative Law. A copy of the proposed amendments to Regulation 1591 is attached.

/s/ Betty T. Yee
Honorable Betty T. Yee, Committee Chair

/s/ Ramon J. Hirsig
Ramon J. Hirsig, Executive Director

BOARD APPROVED

at the November 13, 2008 Board Meeting

/s/ Diane Olson

Diane Olson, Chief
Board Proceedings Division

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances,

dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the

patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be

individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

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(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge

to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION
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October 31, 2008

Dear Interested Party:

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for the November 12, 2008 Business Taxes Committee meeting. This meeting will address the proposed amendments to Regulation 1591, *Medicines and Medical Devices*, regarding ear implant devices.

If you are interested in other topics to be considered by the Business Taxes Committee, you may refer to the "Business Taxes Committee" page on the Board's Internet web site (http://www.boe.ca.gov/meetings/btcommittee.htm) for copies of Committee discussion or issue papers, minutes, a procedures manual, and a materials preparation and review schedule arranged according to subject matter and meeting date.

Thank you for your input on these issues. I look forward to seeing you at the Business Taxes Committee meeting at **9:30 a.m.** on **November 12, 2008,** in Room 121 at the address shown above.

Sincerely,

Randie L. Henry, Deputy Director
Sales and Use Tax Department

RLH:lrc

Enclosures

cc: (all with enclosures)
Honorable Judy Chu, Ph.D., Chair, Fourth District
Honorable Betty T. Yee, Vice Chairwoman, First District (MIC 71)
Honorable Bill Leonard, Member, Second District (MIC 78)
Honorable Michelle Steel, Member, Third District
Honorable John Chiang, State Controller, c/o Ms. Marcy Jo Mandel (via e-mail)

Mr. Steve Shea, Board Member's Office, Fourth District (via e-mail)
Mr. Mark Ibele, Board Member's Office, Fourth District (via e-mail)
Mr. Alan LoFaso, Board Member's Office, First District (via e-mail)
Ms. Sabina Crocette, Board Member's Office, First District (via e-mail)
Mr. Gary Qualset, Board Member's Office, First District (via e-mail)
Ms. Mengjun He, Board Member's Office, First District (via e-mail)
Ms. Amber Kemp, Board Member's Office, First District (via e-mail)
Mr. Lee Williams, Board Member's Office, Second District (via e-mail)
Mr. Ken Maddox, Board Member's Office, Third District (via e-mail)
Mr. Neil Shah, Board Member's Office, Third District (via e-mail)
Ms. Elizabeth Maeng, Board Member's Office, Third District (via e-mail)
Ms. Christina Rueck, Board Member's Office, Third District (via e-mail)
Ms. Melanie Darling, State Controller's Office (via e-mail)
Mr. Ramon J. Hirsig (via e-mail)
Ms. Kristine Cazadd (via e-mail)
Mr. Jeff Vest (via e-mail)
Mr. Robert Lambert (via e-mail)
Mr. Randy Ferris (via e-mail)
Mr. David Levine (via e-mail)
Mr. Timothy Treichelt (via e-mail)
Mr. Cary Huxsoll (via e-mail)
Mr. Robert Tucker (via e-mail)
Mr. Todd Gilman (via e-mail)
Ms. Laureen Simpson (via e-mail)
Mr. Robert Ingenito, Jr. (via e-mail)
Mr. Bill Benson (via e-mail)
Ms. Freda Orendt (via e-mail)
Mr. Stephen Rudd (via e-mail)
Mr. Kevin Hanks (via e-mail)
Mr. Jeff McGuire (via e-mail)
Mr. James Kuhl (via e-mail)
Mr. Geoffrey E. Lyle (via e-mail)
Ms. Leila Hellmuth (via e-mail)
Ms. Lynda Cardwell (via e-mail)
Ms. Cecilia Watkins (via e-mail)

AGENDA —November 12, 2008, Business Taxes Committee Meeting

Amend Regulation 1591, Medicines and Medical Devices

Action 1 — Regulation 1591	**Approve and authorize publication of either:**
Issue Paper Alternative 1	Staff's proposed amendments to Regulation 1591, subdivision (b)(2) to: • Clarify that an ear implant includes the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted. **OR**
Issue Paper Alternative 2	Mr. Polley's proposed amendments to Regulation 1591, subdivision (b)(2) to: • Clarify that *all* "permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

AGENDA —November 12, 2008, Business Taxes Committee Meeting

Amend Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by Polley
Action 1 – Regulation 1591, Subdivision (b)(2)	(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components that operate together as one device in	(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components.

AGENDA —November 12, 2008, Business Taxes Committee Meeting

Amend Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by Polley
	and on the person in whom the device is implanted. Sutures are also included whether or not they are permanently implanted. non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture. Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.	Sutures are also included whether or not they are permanently implanted. non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture. Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

Issue Paper Number **08-012**

BOARD OF EQUALIZATION
KEY AGENCY ISSUE

- ☐ Board Meeting
- ☒ Business Taxes Committee
- ☐ Customer Services and Administrative Efficiency Committee
- ☐ Legislative Committee
- ☐ Property Tax Committee
- ☐ Other

Proposed Amendments to Regulation 1591, *Medicines and Medical Devices,* Regarding Ear Implant Devices

I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be amended to clarify the application of tax to sales of ear implant devices with their mutually dependent internal and external components?

II. Alternative 1 – Staff Recommendation

Staff recommends amending Regulation 1591, subdivision (b)(2), to clarify that an ear implant includes the interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted, to assist in the ongoing functioning of the ear. When the sale of the ear implant qualifies for exemption from tax, the exemption extends to the sale of the interdependent external components.

Staff's proposed amendments are reflected in Exhibit 2.

III. Alternative 2 – Other Alternative Considered

As proposed by Mr. Terry L. Polley of the firm Ajalat, Polley, Ayoob & Matarese, amend Regulation 1591, subdivision (b)(2), to include in the definition of "permanently implanted articles" the interdependent internal and external components of an implanted article, which operate together as one device, in and on the person in whom the device is implanted. Unlike staff's proposed amendment, which is limited to clarification regarding ear implants, this amendment would clarify the application of tax to *all* permanently implanted articles and the implanted article's interdependent external components.

Mr. Polley's proposed amendments are reflected in Exhibit 3.

IV. Background

Revenue and Taxation Code (RTC) section 6369, interpreted and implemented by Regulation 1591, provides that sales of medicines furnished for the treatment of a human being are exempt from sales or use tax if they are sold or furnished under certain conditions, as described in subdivisions (a)(1) through (a)(6) of that section. The term "medicines" is defined by RTC section 6369, subdivision (c), in part, to mean and include "bone screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body."

Regulation 1591, subdivision (b)(2), provides in part and with emphasis added:

> "Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines...."
>
> "Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and **ear implants**."

On February 27, 2008, the Board of Equalization (Board) heard a sales and use tax appeals case regarding the sales of cochlear implant devices. At issue was whether sales of the external components of the ear implant device qualified for exemption from tax in the same manner as the permanently implanted internal components. The petitioner explained that the internal and external components of the ear implant device are effectively one device, with each component mutually dependent on the other to function. Together, the internal and external components of the ear implant device assist in the functioning of the ear, each necessary and integral to the ongoing function of the ear and, as such, both qualify as "medicines." The Board agreed with the petitioner and instructed staff to amend Regulation 1591 to clarify the matter.

Staff and interested parties met on July 16, 2008, to discuss staff's proposed language to amend Regulation 1591. Based on discussions at the meeting, staff modified its proposed regulatory amendments for clarity and to remove any examples of qualifying components since the nature of the components could vary depending on the type of ear implant device.

Staff and interested parties also met on September 9, 2008, to discuss the changes made to staff's initial revisions to Regulation 1591 suggested during the first interested parties meeting and a proposal from Mr. Polley to expand the proposed amendments to subdivision (b)(2) to apply to *all* permanently implanted articles, not just ear implants. Staff considered the suggested expansion; however, since it is believed outside the scope of the direction from the Board, staff's proposed amendments remain specific to ear implants. Staff's proposed amendments are reflected in Exhibit 2. Mr. Polley's proposed amendments are reflected in Exhibit 3.

The Business Taxes Committee is scheduled to discuss the proposed amendments at its meeting on November 12, 2008.

V. Discussion

As provided by Regulation 1591, permanently implanted articles, the sales of which qualify for exemption from tax when certain conditions are met, include articles that are implanted in the human body to assist in the functioning of any natural organ (e.g., heart), artery (e.g., blood vessels that carry blood away from the heart), vein (e.g., blood vessels that carry blood to the heart) or limb and which remain or dissolve in the body. It appears that most qualifying articles, which are intended to function in this manner, are fully implanted in the body; however, this is not currently the case with an ear implant, as discussed below.

Ear implants – In general, an ear implant is a permanently implanted device, which is surgically implanted into the ear (i.e., inner, middle, or outer ear) or surrounding area to assist in, rather than replace, the functioning of the ear. The ear implant generally consists of internal and external components that effectively function together as one unit with each component mutually dependent on the other to function. Notable for all of the interdependent components is the fact that they function together "in or on" the person in whom the device is implanted.

There are different types of ear implants currently available for surgical implanting. The implant and the technology used differ depending on the damage to the ear or nature of the hearing loss. For example, an ear implant may use electrodes implanted in the inner ear (cochlea) to stimulate the auditory nerve with electrical signals the brain can interpret as sound *or* it may penetrate into the auditory portion of the brainstem to produce localized stimulation of the cochlear nucleus and send sound signals to the brain. Unlike hearing aids, these implants do not amplify sound, but work by directly stimulating any functioning auditory nerves inside the cochlea with the electric field stimulated through an electric impulse.

Ear implants generally consist of an external component that includes a microphone and speech/audio processor and an implanted component that generally includes the electronic housing and the attached electrodes. The interdependent external components of the ear implant generally include items such as a coil and magnet, with its protective cover, coil plug, connecting pins and cable; a speech/audio processor with the required connecting pins, microphone, and internal electronics; a battery pack/control unit, with the necessary batteries, connecting pins, and cables; and a headpiece or ear hook. Combined, the external components can consist of numerous parts that may require replacement.

There are also numerous accessories available for persons with an ear implant that are not an interdependent component of the implant. For example, items such as an auxiliary microphone for use with hearing-compatible telephones or for use in loud environments, microphone or processor test devices, system sensor/diagnostic tools, microphone testers, battery or power cell charging systems and car adapters, travel cases, sport carrying cases, key cases that also hold a spare power cell, and tote bags are available for persons with a cochlear implant. There are also similar accessories available for the other types of ear implants.

Replacement components – For the purposes of Regulation 1591, subdivision (b)(2), the exemption for the sale of an ear implant and its interdependent components would also apply to the sale of replacement components or upgrades to such components when they replace or upgrade the interdependent components originally provided as part of the ear implant. For example, if a speech/audio processor originally provided to a patient as a component of his or her cochlear implant were damaged, the sale of a replacement processor or one of its functional internal components would qualify for exemption from tax in the same manner as the original component. Replacement of the processor or its internal component would be necessary for the ongoing functioning of the ear implant.

Accessories for the implant – As noted previously, there are various accessories available to a person with an ear implant. Unlike the replacement of an interdependent component of an ear implant, however, the sale of these items would not qualify as the sale of an exempt "medicine." Although the accessories may be provided or sold to the patient separately or for a single price with the implant, the accessories are not an interdependent component of the implant, nor do they assist in the ongoing functioning of the ear. Since the implanted device can function effectively without these items, they would be excluded from the definition of "medicines." This would also be true for the programming software used to create, adjust, fine tune, or optimize the sound/speech processing programs.

Interested party submission – Prior to the second interested parties meeting held on September 9, 2008, staff received a submission proposing that staff's amendment to Regulation 1591, subdivision (b)(2), be expanded to apply to all permanently implanted articles, not just ear implants. As explained by Mr. Polley in his August 26, 2008 submission, "an auditor may draw the negative implication that interdependent external parts of other implants do not qualify [as medicines]." Mr. Polley believes such an expansion will prevent other taxpayers from having to take cases similar to the cochlear implant case to the Board in the future.

VI. Alternative 1 - Staff Recommendation

A. Description of Alternative 1

Staff recommends that Regulation 1591 be amended to clarify that tax does not apply to sales of the interdependent internal and external components of an *ear implant* that operate together as one device in and on the person in whom the device is implanted. Such components function together with the implant as one unit, which together assist in the functioning of the ear.

As noted under Alternative 2, both staff and Mr. Polley propose to amend Regulation 1591, subdivisions (b)(2) to clarify the application of tax to sales of the interdependent internal and external components of a permanently implanted article. However, staff's proposed amendment to subdivision (b)(2) is limited to clarification regarding sales of ear implants, whereas Mr. Polley's proposed amendment clarifies the application of tax to all permanently implanted articles, including ear implants. In essence, Mr. Polley's proposed amendment extends the Board's decision in the February 27, 2008 appeals hearing to any permanently implanted article, except when the interdependent components are otherwise excluded from the definition of "medicines."

Proposed amendments

In holding with the direction of the Board, staff recommends that, in addition to the two minor punctuation edits shown in bold text with strikeout and underline (edits agreed to by Mr. Polley), the second paragraph of subdivision (b)(2) be amended as follows:

> (2) PERMANENTLY IMPLANTED ARTICLES. ....Permanently implanted articles include, but are not limited to~~,~~**:** permanently implanted artificial sphincters; bone screws and bone pins~~,~~**;** ... and ear implants, including the ear implant's interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted.

Staff's proposed amendments to Regulation 1591 are reflected in Exhibit 2.

B. Pros of Alternative 1

- The proposed amendments clarify that the internal and external components of an ear implant, which are mutually dependent on the other to function, are effectively one device.
- The proposed amendments are specific to ear implants, which staff believes is consistent with the direction of the Board.
- The proposed amendments clarify that when the interdependent external components of an ear implant are worn "on" the person in whom the device is implanted such components are included in the definition of a permanently implanted article in the same manner as the ear implant.

C. Cons of Alternative 1

- The proposed amendments do not clarify whether the interdependent components of other implanted articles qualify as "medicines."
- Since the proposed amendments are limited to ear implants, this may be perceived by some as an inconsistent application of the law.

D. Statutory or Regulatory Change for Alternative 1

No statutory change is required. However, staff's recommendation does require the amendment of Regulation 1591.

E. Operational Impact of Alternative 1

Staff will notify taxpayers of the amendments to Regulation 1591 through the Tax Information Bulletin (TIB).

F. Administrative Impact of Alternative 1

1. Cost Impact

The workload associated with publishing the regulation and TIB is routine. Any corresponding cost would be absorbed within the Board's existing budget.

2. Revenue Impact

None. See Revenue Estimate (Exhibit 1)

G. Taxpayer/Customer Impact of Alternative 1

Overall taxpayer impact is minimal since the proposed amendments clarify rather than change the current application of tax.

H. Critical Time Frames of Alternative 1

Implementation will take place 30 days following approval of the regulation by the State Office of Administrative Law.

VII. Alternative 2 – Mr. Polley's Proposal

A. Description of Alternative 2

Like staff, Mr. Polly recommends that Regulation 1591 be amended to clarify that tax does not apply to the sale of the interdependent internal and external components of an ear implant that operate together as one device in and on the person in whom the device is implanted. However, consistent with what he believes to be the intent of the Board, Mr. Polley proposes that Regulation 1591, subdivision (b)(2), be amended to clarify the application of tax to sales of the interdependent internal and external components of *any* implanted article, which operate together as one device to assist in the functioning of any natural organ, artery, vein, or limb, except for devices excluded from the definition of "medicines." Mr. Polley believes the amendment to subdivision (b)(2) is necessary for consistency and clarity.

Whereas staff's proposal limits the amendment to Regulation 1591 to clarification regarding the application of tax to sales of the interdependent internal and external components of an ear implant, Mr. Polley's proposal would effectively extend the principle related to ear implants to other similarly situated articles and provide clarification regarding this principle in the regulation. Devices that are excluded from the definition of "medicines" by statute, would not qualify even though the device may consist of interdependent components, which effectively function together as one device.

As stated previously, staff does not believe the Board intended for Regulation 1591 to be amended to clarify the application of tax to sales of other similarly situated implanted articles when they instructed staff to amend Regulation 1591.

Proposed amendments

Mr. Polley proposes that the first paragraph of subdivision (b)(2) be amended to provide that:

> "(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted...."

Like staff, Mr. Polley also recommends that the second paragraph of subdivision (b)(2) be amended to clarify the application of tax to ear implants specifically; however, since the principle behind the Board's decision in the appeals case is reflected in the proposed amendment to the first paragraph, the paragraph should be amended as follows:

> ....Permanently implanted articles include, but are not limited to~~,~~: permanently implanted artificial sphincters; bone screws and bone pins~~,~~; ... and ear implants, including the ear implant's interdependent internal and external components.

Mr. Polley's proposed amendments to Regulation 1591 are reflected in Exhibit 3.

B. Pros of Alternative 2

- The proposed amendments clarify that the internal and external components of an implant, which are mutually dependent on the other to function, are effectively one device.
- The proposed amendments clarify the application of tax to sales of *all* implanted articles, which may be perceived as a more consistent application of the law.

C. Cons of Alternative 2

- The proposed amendments appear broader than intended by the Board.

D. Statutory or Regulatory Change for Alternative 2

No statutory change is required. However, proposal does require the amendment of Regulation 1591.

E. Operational Impact of Alternative 2

Staff will notify taxpayers of the amendments to Regulation 1591 through the Tax Information Bulletin (TIB).

F. Administrative Impact of Alternative 2

1. Cost Impact

The workload associated with publishing the regulation and TIB is routine. Any corresponding cost would be absorbed within the Board's existing budget.

2. Revenue Impact

None – See Revenue Estimate (Exhibit 1)

G. Taxpayer/Customer Impact of Alternative 2

Overall taxpayer impact would be minimal.

H. Critical Time Frames of Alternative 2

Implementation will take place 30 days following approval of the regulation by the State Office of Administrative Law.

Preparer/Reviewer Information

Prepared by: Tax Policy Division

Current as of: 10/30/2008

REVENUE ESTIMATE

STATE OF CALIFORNIA
BOARD OF EQUALIZATION

BOARD OF EQUALIZATION
REVENUE ESTIMATE

Proposed Amendments to Regulation 1591, *Medicines and Medical Devices,* Regarding Ear Implant Devices

Alternative 1 – Staff Recommendation

Staff recommends amending Regulation 1591, subdivision (b)(2), to clarify that an ear implant includes the interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted, to assist in the ongoing functioning of the ear. When the sale of the ear implant qualifies for exemption from tax, the exemption extends to the sale of the interdependent external components.

Alternative 2 - Other Alternative Considered

As proposed by Mr. Terry L. Polley of the firm Ajalat, Polley, Ayoob & Matarese, amend Regulation 1591, subdivision (b)(2), to include in the definition of "permanently implanted articles" the interdependent internal and external components of an implanted article, which operate together as one device, in and on the person in whom the device is implanted. Unlike staff's proposed amendment, which is limited to clarification regarding ear implants, this amendment would clarify the application of tax to *all* permanently implanted articles and the implanted article's interdependent external components."

Background, Methodology, and Assumptions

Alternative 1 – Staff Recommendation

There is nothing in staff recommendation that would impact sales and use tax revenue. Staff recommendation clarifies that tax does not apply to the sale of the interdependent internal and external components of an ear implant that operate together as one device in and on the person in whom the device is implanted. Such components function together with the implant as one unit, which together assist in the functioning of the ear.

Also, staff recommendation clarifies the application of tax to sales of the interdependent internal and external components of a permanently implanted device. However, staff's proposed

amendment is limited to ear implants, whereas the other alternative's proposed amendment is intended to apply to all permanently implanted articles, including ear implants.

Alternative 2 - Other Alternative Considered

There is nothing in the alternative 2 that would impact sales and use tax revenue. Similar to staff recommendation, alternative 2 would clarify that tax does not apply to the sale of the interdependent internal and external components of an ear implant that operate together as one device in and on the person in whom the device is implanted. However, proponents of alternative 2 believe that, for consistency and clarity, Regulation 1591 (b) (2) should be amended to clarify the application of tax to sales of the interdependent internal and external components of *any* implanted article, which operate together as one device to assist in the functioning of any natural organ, artery, vein, or limb.

Revenue Summary

Alternative 1 – staff recommendation does not have a revenue impact.

Alternative 2 – alternative 2 does not have a revenue impact.

Preparation

Mr. Bill Benson, Jr., Research and Statistics Section, Legislative and Research Division, prepared this revenue estimate. Mr. Robert Ingenito, Jr., Manager, Research and Statistics Section, Legislative and Research Division, and Mr. Jeff McGuire, Tax Policy Manager, Sales and Use Tax Department, reviewed this revenue estimate. For additional information, please contact Mr. Benson at (916) 445-0840.

Current as of October 30, 2008.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances,

dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503.

For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be

individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances,

dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503.

For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

REGULATION HISTORY

TYPE OF REGULATIONS: Sales and Use Tax

REGULATION: 1591

TITLE: *Medicines and Medical Devices*

PREPARATION: Lynda Cardwell/Cecilia Watkins
LEGAL CONTACT: Cary Huxsoll/Robert Tucker

Proposed amendments to Regulation 1591 to clarify that an ear implant includes the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted.

HISTORY OF AMENDMENTS:

11-12-08: Business Taxes Committee (BTC) Meeting

09-09-08: Second Interested Parties Meeting

07-16-08: First Interested Parties Meeting

03-06-08: Topic Placed on BTC Calendar

Sponsor: Alternative 1 – Board Staff
Alternative 2 – Mr. Terry L. Polley of the firm Ajalat, Polley, Ayoob & Matarese

Support: NA

Oppose: NA

BEFORE THE CALIFORNIA STATE BOARD OF EQUALIZATION

450 N Street, Room 121

Sacramento, California

REPORTER'S TRANSCRIPT

NOVEMBER 12, 2008

BUSINESS TAXES COMMITTEE

Reported by: Beverly D. Toms

No. CSR 1662

P R E S E N T

For the Committee	Betty Yee Chair
	Judy Chu Member
	Bill Leonard Member
	Michelle Steel Member
	Marcy Jo Mandel Appearing for John Chiang, State Controller (per Government Code Section 7.9)
	Diane Olson Chief, Board Proceedings Division
Board of Equalization Staff:	Jeff McGuire Sales and Use Tax Department
	Robert Tucker Legal Department

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Sacramento, California

November 12, 2008

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DR. CHU: And now, let's go to the Business Taxes Committee. Ms. Yee.

MS. YEE: Thank you very much. Good morning. We have one agenda item on the Business Taxes Committee agenda. It's the proposed changes to Sales and Use Tax Regulation 1591. Let me have Mr. McGuire introduce the issue.

MR. McGUIRE: Good morning, I'm Jeff McGuire with the Sales and Use Tax Department. With me today is Bob Tucker of our Legal Department.

As Ms. Yee mentioned, we have one agenda item for your consideration today, which involves proposed revisions to Regulation 1591, which is medicines and medical devices. And it specifically is regarding ear implants.

The issue was referred to the committee in response to an appeal before the Board in February of this year. The issue at hand in the appeal was whether an interdependent external component of an ear implant device qualified as an exempt medicine.

The Board did conclude that such devices are exempt and requested that staff amend the regulation to clarify this matter.

We have two alternatives for changing the regulation. The first as recommended by staff would

clarify that an exempt ear implant device includes both the interdependent internal and external components that operate together as one device.

Alternative 2, which is proposed by Mr. Terry Pauli, would also exempt interdependent internal and external components of an ear implant as well as similarly situated devices other than those that are specifically excluded from the definition of medicine.

We're requesting your approval or authorization of -- to publish regulation changes and I don't believe we have any speakers.

MS. YEE: No, there are no speakers signed in. Let -- let me try to do a little refresher here. This -- these proposed changes arose out of an appeal decision that this Board made with respect to cochlear implants. And what I would like to do is actually suggest that we adopt Alternative 2 --

MS. MANDEL: Yes.

MS. YEE: -- and authorize publication because I distinctly remember that the direction from this Board after the decision was to not have to revisit this regulation when there are other similarly situated devices where there is an internal and an external component in order to make the implant fully operational.

So, I -- unless there's disagreement by my colleagues that would be my motion.

MS. MANDEL: I -- I don't have a problem with

that and I -- the way I read the issue paper was that -- that staff's impression was coch -- was the ear implants, and so they were wary of going beyond that. And certainly in the case all of the annotations and support talked for -- for the taxpayer's position talked about integral and necessary -- this was really one entire thing was the device, and the particular problem that staff had was that there was this auditory device exclusion and they weren't sure what to do with this new-fangled cochlear implant thing.

But definitely Alternative 2 seems to be, you know, a complete -- complete alternative on -- on the generalized issue.

MS. YEE: Other comments, Members?

Dr. Chu.

DR. CHU: Well, what is your feedback on that in terms of defining the kind of devices that we would be talking about?

MR. TUCKER: Bob Tucker on behalf of the Legal Department. The staff prepared Alternative 1 because we understood that to be the direction from the Board. However, in Alternative 1 it's included in a non-exhaustive list of examples. Accordingly, we believe it could be applied and would apply to other similarly situated devices.

However, after the recent changes by Mr. Pauli we really see no meaningful distinction between the two proposals.

MS. MANDEL: Yeah, and the concern, I think, would be it's -- it's always very nice when we're sitting here and saying there's no meaningful distinction and then, you know, I always say when we're all gone or when it's down at audit, and then you wind up with Ms. Yee's example of, you know, some other similarly situated thing, and you have someone having a fight with an auditor or perhaps up to the Board saying, well, they specifically didn't choose this other alternative, therefore they really only restricted it to ear implants. And since -- since in your view they're the same, why not take the one that makes it clear that -- that it covers everything.

So that's -- that's kind of how we -- I got -- we got to the --

MS. YEE: Right.

MS. MANDEL: -- place we were at.

MS. YEE: Other questions or concerns?

Okay.

Hearing none, I will proceed to move adoption of Alternative 2 and to authorize publication.

MS. STEEL: Second.

MR. LEONARD: Second.

MS. YEE: Okay. Without objection, such will be the order.

Thank you very much.

That concludes the Business Taxes Committee.

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REPORTER'S CERTIFICATE

State of California)
) ss
County of Sacramento)

I, BEVERLY D. TOMS, Hearing Reporter for the California State Board of Equalization certify that on November 12, 2008 I recorded verbatim, in shorthand, to the best of my ability, the proceedings in the above-entitled hearing; that I transcribed the shorthand writing into typewriting; and that the preceding 6 pages constitute a complete and accurate transcription of the shorthand writing.

Dated: February 2, 2009.

_____

BEVERLY D. TOMS
Hearing Reporter

ESTIMATE OF COST OR SAVINGS RESULTING FROM PROPOSED REGULATORY ACTION

Proposed Amendment of Sales and Use Tax Regulation 1591, *Medicines and Medical Devices*

STATEMENT OF COST OR SAVINGS FOR NOTICE OF PUBLIC HEARING

The State Board of Equalization has determined that the proposed action does not impose a mandate on local agencies or school districts. Further, the Board has determined that the action will result in no direct or indirect cost or savings to any State agency, any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary cost or savings imposed on local agencies, or cost or savings in Federal funding to the State of California.

The cost impact on private persons or businesses will be insignificant. This proposal will not have a significant adverse economic impact on businesses.

This proposal will not be detrimental to California businesses in competing with businesses in other states.

This proposal will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses or create or expand business in the State of California.

Statement Prepared by _____ Date 11-26-2008
Regulations Coordinator

Approved by _____ Date 11/26/08
Chief Counsel

If Costs or Savings are Identified, Signatures of Chief, Fiscal Management Division, and Chief, Board Proceedings Division, are Required

Approved by _____ Date _____
Chief, Financial Management Division

Approved by _____ Date _____
Chief, Board Proceedings Division

NOTE: SAM Section 6660 requires that estimates resulting in cost or savings be submitted for Department of Finance concurrence before the notice of proposed regulatory action is released.

Board Proceedings Division
10/7/05

STATE OF CALIFORNIA

ECONOMIC AND FISCAL IMPACT STATEMENT

(REGULATIONS AND ORDERS)

399 (Rev. 2-98)

See SAM Sections 6600 - 6680 for Instructions and Code Citations

DEPARTMENT NAME	CONTACT PERSON	TELEPHONE NUMBER
State Board of Equalization	Richard E. Bennion	916-445-2130
DESCRIPTIVE TITLE FROM *NOTICE REGISTER* OR FORM 400		**NOTICE FILE NUMBER**
Title 18, Section 1591, Medicines and Medical Devices		Z

ECONOMIC IMPACT STATEMENT

A. ESTIMATED PRIVATE SECTOR COST IMPACTS *(Include calculations and assumptions in the rulemaking record.)*

1. Check the appropriate box(es) below to indicate whether this regulation:

- ☐ a. Impacts businesses and/or employees
- ☐ b. Impacts small businesses
- ☐ c. Impacts jobs or occupations
- ☐ d. Impacts California competitiveness
- ☐ e. Imposes reporting requirements
- ☐ f. Imposes prescriptive instead of performance standards
- ☐ g. Impacts individuals
- ☑ h. None of the above *(Explain below. Complete the Fiscal Impact Statement as appropriate.)*

h. *(cont.)* No significant adverse economic impact on business or employees,small business,jobs or occupations.

(If any box in Items 1 a through g is checked, complete this Economic Impact Statement.)

2. Enter the total number of businesses impacted:_____ Describe the types of businesses *(Include nonprofits)*:_____

Enter the number or percentage of total businesses impacted that are small businesses:_____

Enter the number of businesses that will be created: _____ eliminated: _____

Explain:_____

4. Indicate the geographic extent of impacts: ☐ Statewide ☐ Local or regional *(list areas)*: _____

5. Enter the number of jobs created:_____ or eliminated:_____ Describe the types of jobs or occupations impacted:_____

6. Will the regulation affect the ability of California businesses to compete with other states by making it more costly to produce goods or services here?

☐ Yes ☐ No If yes, explain briefly:_____

B. ESTIMATED COSTS *(Include calculations and assumptions in the rulemaking record.)*

1. What are the total statewide dollar costs that businesses and individuals may incur to comply with this regulation over its lifetime? $_____

a. Initial costs for a small business: $_____ Annual ongoing costs: $_____ Years: _____

b. Initial costs for a typical business: $_____ Annual ongoing costs: $_____ Years: _____

c. Initial costs for an individual: $_____ Annual ongoing costs: $_____ Years: _____

d. Describe other economic costs that may occur:_____

2. If multiple industries are impacted, enter the share of total costs for each industry:_____

_____

3. If the regulation imposes reporting requirements, enter the annual costs a typical business may incur to comply with these requirements. *(Include the dollar costs to do programming, record keeping, reporting, and other paperwork, whether or not the paperwork must be submitted.):* $_____

4. Will this regulation directly impact housing costs? ☐ Yes ☐ No If yes, enter the annual dollar cost per housing unit: $_____ and the number of units:_____

5. Are there comparable Federal regulations? ☐ Yes ☐ No Explain the need for State regulation given the existence or absence of Federal regulations: _____

Enter any additional costs to businesses and/or individuals that may be due to State - Federal differences: $_____

C. ESTIMATED BENEFITS *(Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.)*

1. Briefly summarize the benefits that may result from this regulation and who will benefit:_____

_____

_____

2. Are the benefits the result of: ☐ specific statutory requirements, or ☐ goals developed by the agency based on broad statutory authority?

Explain:_____

3. What are the total statewide benefits from this regulation over its lifetime? $_____

D. ALTERNATIVES TO THE REGULATION *(Include calculations and assumptions in the rulemaking record. Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.)*

1. List alternatives considered and describe them below. If no alternatives were considered, explain why not:_____

_____

_____

2. Summarize the total statewide costs and benefits from this regulation and each alternative considered:

Regulation:	Benefit: $_____	Cost: $_____
Alternative 1:	Benefit: $_____	Cost: $_____
Alternative 2:	Benefit: $_____	Cost: $_____

3. Briefly discuss any quantification issues that are relevant to a comparison of estimated costs and benefits for this regulation or alternatives:_____

_____

_____

4. Rulemaking law requires agencies to consider performance standards as an alternative, if a regulation mandates the use of specific technologies or equipment, or prescribes specific actions or procedures. Were performance standards considered to lower compliance costs? ☐ Yes ☐ No

Explain:_____

E. MAJOR REGULATIONS *(Include calculations and assumptions in the rulemaking record.)*
Cal/EPA boards, offices and departments are subject to the following additional requirements per Health and Safety Code section 57005.

ECONOMIC AND FISCAL IMPACT STATEMENT *cont. (STD. 399, Rev. 2-98)*

1. Will the estimated costs of this regulation to California business enterprises exceed $10 million ? ☐ Yes No *(If No, skip the rest of this section)*

2. Briefly describe each equally as effective alternative, or combination of alternatives, for which a cost-effectiveness analysis was performed:

   Alternative 1:_____

   Alternative 2:_____

3. For the regulation, and each alternative just described, enter the estimated total cost and overall cost-effectiveness ratio:

   Regulation: $ _____ Cost-effectiveness ratio: _____

   Alternative 1: $ _____ Cost-effectiveness ratio: _____

   Alternative 2: $ _____ Cost-effectiveness ratio: _____

FISCAL IMPACT STATEMENT

A. FISCAL EFFECT ON LOCAL GOVERNMENT *(Indicate appropriate boxes 1 through 6 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years)*

☐ 1. Additional expenditures of approximately $_____in the current State Fiscal Year which are reimbursable by the State pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code. Funding for this reimbursement:

☐ a. is provided in (Item_____,Budget Act of_____) or (Chapter_____,Statutes of_____

☐ b. will be requested in the_____Governor's Budget for appropriation in Budget Act of _____.
(FISCAL YEAR)

☐ 2. Additional expenditures of approximately $_____in the current State Fiscal Year which are not reimbursable by the State pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code because this regulation:

☐ a. implements the Federal mandate contained in_____

☐ b. implements the court mandate set forth by the_____

court in the case of_____vs._____

☐ c. implements a mandate of the people of this State expressed in their approval of Proposition No._____at the_____ election;
(DATE)

☐ d. is issued only in response to a specific request from the _____

_____, which is/are the only local entity(s) affected;

☐ e. will be fully financed from the _____authorized by Section
(FEES, REVENUE, ETC.)

_____of the_____Code;

☐ f. provides for savings to each affected unit of local government which will, at a minimum, offset any additional costs to each such unit.

☐ 3. Savings of approximately $_____annually.

☐ 4. No additional costs or savings because this regulation makes only technical, non-substantive or clarifying changes to current law and regulations.

ECONOMIC AND FISCAL IMPACT STATEMENT *cont. (STD. 399, Rev. 2-98)*

☑ 5. No fiscal impact exists because this regulation does not affect any local entity or program.

☐ 6. Other.

B. FISCAL EFFECT ON STATE GOVERNMENT *(Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.)*

☐ 1. Additional expenditures of approximately $_____ in the current State Fiscal Year. It is anticipated that State agencies will:

☐ a. be able to absorb these additional costs within their existing budgets and resources.

☐ b. request an increase in the currently authorized budget level for the _____ fiscal year.

☐ 2. Savings of approximately $_____ in the current State Fiscal Year.

☑ 3. No fiscal impact exists because this regulation does not affect any State agency or program.

☐ 4. Other.

C. FISCAL EFFECT ON FEDERAL FUNDING OF STATE PROGRAMS *(Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.)*

☐ 1. Additional expenditures of approximately $_____ in the current State Fiscal Year.

☐ 2. Savings of approximately $_____ in the current State Fiscal Year.

☑ 3. No fiscal impact exists because this regulation does not affect any federally funded State agency or program.

☐ 4. Other.

SIGNATURE ✍		TITLE Regulations Coordinator
AGENCY SECRETARY [1] APPROVAL/CONCURRENCE	✍ Diane G. Olson	DATE 11/26/08
DEPARTMENT OF FINANCE [2] APPROVAL/CONCURRENCE	PROGRAM BUDGET MANAGER ✍ Exempt under SAM section 6660	DATE

1. *The signature attests that the agency has completed the STD. 399 according to the instructions in SAM sections 6600-6680, and understands the impacts of the proposed rulemaking. State boards, offices, or departments not under an Agency Secretary must have the form signed by the highest ranking official in the organization.*

2. *Finance approval and signature is required when SAM sections 6600-6670 require completion of the Fiscal Impact Statement in the STD. 399.*

STATE OF CALIFORNIA–OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-08)

OAL FILE NUMBERS	NOTICE FILE NUMBER	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
	Z-2008-1202-01		

For use by Office of Administrative Law (OAL) only

RECEIVED FOR FILING PUBLICATION DATE

DEC 0 2 2008 DEC 1 2 2008

Office of Administrative Law

NOTICE | REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY
State Board of Equalization

AGENCY FILE NUMBER (If any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
Ear Implant Devices	18	1591	December 12, 2008

3. NOTICE TYPE	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
☐ Notice re Proposed Regulatory Action ☒ Other	Richard E. Bennion	(916) 445-2130	(916) 324-3984

OAL USE ONLY	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE
	☐ Approved as Submitted ☐ Approved as Modified ☐ Disapproved/ Withdrawn		

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S)

1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)

SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) **(Including title 26, if toxics related)**

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)

TITLE(S)

ADOPT

AMEND

REPEAL

3. TYPE OF FILING

- ☐ Regular Rulemaking (Gov. Code §11346)
- ☐ Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)
- ☐ Emergency (Gov. Code, §11346.1(b))
- ☐ Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
- ☐ Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
- ☐ Emergency Readopt (Gov. Code, §11346.1(h))
- ☐ File & Print
- ☐ Other (Specify) _____
- ☐ Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
- ☐ Print Only

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

- ☐ Effective 30th day after filing with Secretary of State
- ☐ Effective on filing with Secretary of State
- ☐ §100 Changes Without Regulatory Effect
- ☐ Effective other (Specify) _____

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

- ☐ Department of Finance (Form STD. 399) (SAM §6660)
- ☐ Fair Political Practices Commission
- ☐ State Fire Marshal
- ☐ Other (Specify) _____

7. CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional)
Richard E. Bennion			

8. **I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.**

SIGNATURE OF AGENCY HEAD OR DESIGNEE | DATE

TYPED NAME AND TITLE OF SIGNATORY

Title 18. State Board of Equalization

NOTICE IS HEREBY GIVEN

The State Board of Equalization (Board), pursuant to the authority vested in it by section 15606, subdivision (a), of the Government Code, proposes to amend Regulation 1591, *Medicines and Medical Devices*, in Title 18, Division 2, Chapter 4, Articles 19 and 20 of the California Code of Regulations, relating to regulatory changes to clarify that all "permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

"Permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines.

A public hearing on the proposed regulations will be held in Room 121, 450 N Street, Sacramento, at 9:30 a.m., or as soon thereafter as the matter may be heard, on Tuesday, February 3, 2009. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by February 3, 2009.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Revenue and Taxation Code (RTC) section 6369, interpreted and implemented by Regulation 1591, provides that sales of medicines furnished for the treatment of a human being are exempt from sales or use tax if they are sold or furnished under certain conditions, as described in subdivisions (a)(1) through (a)(6) of that section. The term "medicines" is defined by RTC section 6369, subdivision (c), in part, to mean and include "bone screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body."

Regulation 1591, subdivision (b)(2), provides in part and with emphasis added:

"Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines...."

"Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants."

The proposed amendments would amend regulation 1591(b)(2) to clarify that tax does not apply to the sale of *all* "permanently implanted articles" including an implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendments do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5, subdivision (a)(8), the Board of Equalization makes an initial determination that the adoption of the amendments to Regulation 1591 will have no significant statewide adverse economic impact directly affecting business.

The adoption of the proposed amendments to these regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The amendments to the regulations as proposed will not be detrimental to California businesses in competing with businesses in other states.

The proposed regulations may affect small business.

COST IMPACT ON PRIVATE PERSON OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

FEDERAL REGULATIONS

Regulations 1591 and the proposed changes have no comparable federal regulations.

AUTHORITY

Section 7051, Revenue and Taxation Code.

REFERENCE

Section 6369, Revenue and Taxation Code.

CONTACT

Questions regarding the substance of the proposed regulation should be directed to Mr. Cary Huxsoll (916) 324-2641, at 450 N Street, Sacramento, CA 95814, e-mail Cary.Huxsoll@boe.ca.gov or MIC:82, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0082.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Mr. Rick Bennion, Regulations Coordinator, telephone (916) 445-2130, fax (916) 324-3984 , e-mail Richard.Bennion@boe.ca.gov or by mail at State Board of Equalization, Attn: Rick Bennion MIC:81, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0080.

ALTERNATIVES CONSIDERED

The Board determined that no reasonable alternative considered by it or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored and strikeout version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed regulation are available on the Internet at the Board's Web site http://www.boe.ca.gov.

AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's Web site following its public hearing of the proposed regulation. It will also be available for public inspection at 450 N Street, Sacramento, California.

ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Mr. Bennion. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility.A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and

IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be

individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed

physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIETARY SUPPLEMENTS AND ADJUNCTS. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

NOTE: Authority cited: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006 and 6369, Revenue and Taxation Code; and sections 1200, 1200.1, 1204.1, and 1250, Health and Safety Code.

Bennion, Richard

From: Madrigal, Claudia [Claudia.Madrigal@BOE.CA.GOV]
Sent: Friday, December 12, 2008 9:59 AM
To: BOE_REGULATIONS@LISTSERV.CAHWNET.GOV
Subject: State Board of Equalization - Announcement of Regulatory Change

This email is being redistributed. In the previous email the link to the Regulation was inactive.

The State Board of Equalization will hold a public hearing regarding the amendment of Sales and Use Tax Regulation 1591, *Medicines and Medical Devices*, in relating to regulatory changes to clarify that all "permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines." The public hearing on the proposed regulation will be held in Room 121, 450 N Street, Sacramento, at 9:30 a.m., or as soon thereafter as the matter may be heard on Tuesday, February 3, 2009.

To view the notice of hearing, initial statement of reasons, proposed text, and history click on the following link: http://www.boe.ca.gov/regs/reg1591.html

Questions regarding the substance of the proposed amendments to Regulation 1591 should be directed to: Mr. Cary Huxsoll, Tax Counsel, at 450 N Street, MIC:82, Sacramento, CA 94279-0082, email Cary.Huxsoll@boe.ca.gov , telephone (916) 324-2641, or FAX (916) 323-3387.

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Fiscal Impact on State Government. This regulatory action will have no fiscal impact on any state entity or program.

Fiscal Impact on Federal Funding of State Programs. This regulatory action will have no fiscal impact on the federal funding of any state program or entity.

AUTHORITY

Sections 83112 and 83113 provide that the Fair Political Practices Commission may adopt, amend, and rescind rules and regulations to carry out the purposes and provisions of the Political Reform Act.

REFERENCE

The purpose of this regulation is to implement, interpret and make specific Government Code Sections 82027.5 and 82047.5.

CONTACT

Any inquiries concerning this proposal should be made to Hyla Wagner, Fair Political Practices Commission, 428 J Street, Suite 620, Sacramento, California 95814, telephone: (916) 322–5660. Proposed regulatory language can be accessed at www.fppc.ca.gov.

TITLE 18. STATE BOARD OF EQUALIZATION

NOTICE IS HEREBY GIVEN

The State Board of Equalization (Board), pursuant to the authority vested in it by section 15606, subdivision (a), of the Government Code, proposes to amend Regulation 1591, *Medicines and Medical Devices*, in Title 18, Division 2, Chapter 4, Articles 19 and 20 of the California Code of Regulations, relating to regulatory changes to clarify that all "permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

A public hearing on the proposed regulations will be held in Room 121, 450 N Street, Sacramento, at 9:30 a.m., or as soon thereafter as the matter may be heard, on Tuesday, February 3, 2009. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by February 3, 2009.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Revenue and Taxation Code (RTC) section 6369, interpreted and implemented by Regulation 1591, provides that sales of medicines furnished for the treatment of a human being are exempt from sales or use tax if they are sold or furnished under certain conditions, as described in subdivisions (a)(1) through (a)(6) of that section. The term "medicines" is defined by RTC section 6369, subdivision (c), in part, to mean and include "bone screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body."

Regulation 1591, subdivision (b)(2), provides in part and with emphasis added:

"Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. . . ."

"Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants."

The proposed amendments would amend regulation 1591(b)(2) to clarify that tax does not apply to the sale of *all* "permanently implanted articles" including an implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendments do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of

the Government Code or other non–discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5, subdivision (a)(8), the Board of Equalization makes an initial determination that the adoption of the amendments to Regulation 1591 will have no significant statewide adverse economic impact directly affecting business.

The adoption of the proposed amendments to these regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The amendments to the regulations as proposed will not be detrimental to California businesses in competing with businesses in other states.

The proposed regulations may affect small business.

COST IMPACT ON PRIVATE PERSON OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

FEDERAL REGULATIONS

Regulations 1591 and the proposed changes have no comparable federal regulations.

AUTHORITY

Section 7051, Revenue and Taxation Code.

REFERENCE

Section 6369, Revenue and Taxation Code.

CONTACT

Questions regarding the substance of the proposed regulation should be directed to Mr. Cary Huxsoll (916) 324–2641, at 450 N Street, Sacramento, CA 95814, e–mail Cary.Huxsoll@boe.ca.gov or MIC:82, P.O. Box 942879, 450 N Street, Sacramento, CA 94279–0082.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Mr. Rick Bennion, Regulations Coordinator, telephone (916) 445–2130, fax (916) 324–3984, e–mail Richard.Bennion@boe.ca.gov or by mail at State Board of Equalization, Attn: Rick Bennion MIC:81, P.O. Box 942879, 450 N Street, Sacramento, CA 94279–0080.

ALTERNATIVES CONSIDERED

The Board must determine that no reasonable alternative considered by it or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored and strikeout version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed regulation are available on the Internet at the Board's Web site http://www.boe.ca.gov.

AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's Web site following its public hearing of the proposed regulation. It will also be available for public inspection at 450 N Street, Sacramento, California.

ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be

mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Mr. Bennion. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.

TITLE 20. CALIFORNIA ENERGY COMMISSION

In the Matter of,

Proposed Adoption of Regulations for the Administration of the Alternative and Renewable Fuel and Vehicle Technology Program

Docket No. 08–OIR–1

NOTICE OF STAFF MEETING

Notice of Proposed Action
Adoption of Regulations to Allocate Funds as Established Through the Alternative and Renewable Fuel and Vehicle Technology Program

The California Energy Commission (Energy Commission) proposes to adopt new regulations to define the administration of the Alternative and Renewable Fuel and Vehicle Technology Program in line with the Energy Commission's authority under Health and Safety Code section 44270 et seq. The regulations would implement, interpret, and make specific Health and Safety Code sections 44270–44274, which were added in 2007 (Assembly Bill 118, Núñez, Chapter 750, Statutes of 2007). The proposed action is authorized under Public Resources Code sections 25213 and 25218(e) and Health and Safety Code sections 44271 and 44271.5.

NOTICE THAT PUBLIC HEARING IS SCHEDULED

The date set for the adoption of regulations at a public hearing is:

Wednesday, January 28, 2009
10 a.m.
CALIFORNIA ENERGY COMMISSION
First Floor, Hearing Room A
1516 Ninth Street
Sacramento, California
(Wheelchair Accessible)

ORAL AND WRITTEN STATEMENTS

Interested persons wishing to comment on the proposed regulations must submit their comments in writing to the Energy Commission by January 26, 2009. All comments must be identified with **"Docket No. 08–OIR–1"** and may be submitted in one of three ways:

1) Mailing them to:

   Docket Unit
   California Energy Commission
   Docket No. 08–OIR–1
   1516 9th Street, MS–4
   Sacramento, CA 95814

2) E–mailing them to: [DOCKET@energy.state.ca.us], or
3) Faxing them to Dockets at (916) 654–4354

COPIES OF THE INITIAL STATEMENT OF REASONS AND THE TEXT

The Energy Commission has prepared an initial statement of reasons for the proposed regulations. To obtain a copy of the initial statement of reasons or the express terms of the proposed regulations, please visit the Energy Commission's website at [www.energy.ca.gov/ab118/index.html] or contact Aleecia Macias at (916) 654–4526 or by e–mail at [amacias@energy.state.ca.us].

INTERNET ACCESS

The Energy Commission maintains a website to facilitate public access to documents prepared and considered as part of this rulemaking proceeding. Documents prepared by the Energy Commission for this rulemaking, including this notice of proposed action, the text of the proposed regulations, the initial statement of reasons, and the economic and fiscal impact statement, as well as any other document in the rulemaking file, have been posted at [www.energy.ca.gov/ab118/index.html].

COPY OF THE FINAL STATEMENT OF REASONS

At the conclusion of the rulemaking, persons may obtain a copy of the final statement of reasons once it has been prepared by visiting the Energy Commission's website at [www.energy.ca.gov/ab118/index.html] or contacting Aleecia Macias at (916) 654–4526 or by e–mail at [amacias@energy.state.ca.us].

STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION
150 N STREET, SACRAMENTO, CALIFORNIA
PO BOX 942879, SACRAMENTO, CALIFORNIA 94279-80
916-445-2130 • FAX 916-324-3984
www.boe.ca.gov

December 12, 2008

To Interested Parties:

Notice of Proposed Regulatory Action
by the
State Board of Equalization

Proposed to Adopt Regulation 1591, *Medicines and Medical Devices*

NOTICE IS HEREBY GIVEN

The State Board of Equalization (Board), pursuant to the authority vested in it by section 15606, subdivision (a), of the Government Code, proposes to amend Regulation 1591, *Medicines and Medical Devices*, in Title 18, Division 2, Chapter 4, Articles 19 and 20 of the California Code of Regulations, relating to regulatory changes to clarify that all "permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

"Permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines.

A public hearing on the proposed regulations will be held in Room 121, 450 N Street, Sacramento, at 9:30 a.m., or as soon thereafter as the matter may be heard, on Tuesday, February 3, 2009. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by February 3, 2009.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Revenue and Taxation Code (RTC) section 6369, interpreted and implemented by Regulation 1591, provides that sales of medicines furnished for the treatment of a human being are exempt from sales or use tax if they are sold or furnished under certain conditions, as described in subdivisions (a)(1) through (a)(6) of that section. The term "medicines" is defined by RTC

section 6369, subdivision (c), in part, to mean and include "bone screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body."

Regulation 1591, subdivision (b)(2), provides in part and with emphasis added:

"Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines...."

"Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants."

The proposed amendments would amend regulation 1591(b)(2) to clarify that tax does not apply to the sale of *all* "permanently implanted articles" including an implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendments do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5, subdivision (a)(8), the Board of Equalization makes an initial determination that the adoption of the amendments to Regulation 1591 will have no significant statewide adverse economic impact directly affecting business.

The adoption of the proposed amendments to these regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The amendments to the regulations as proposed will not be detrimental to California businesses in competing with businesses in other states.

The proposed regulations may affect small business.

COST IMPACT ON PRIVATE PERSON OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

FEDERAL REGULATIONS

Regulations 1591 and the proposed changes have no comparable federal regulations.

AUTHORITY

Section 7051, Revenue and Taxation Code.

REFERENCE

Section 6369, Revenue and Taxation Code.

CONTACT

Questions regarding the substance of the proposed regulation should be directed toMr. Cary Huxsoll (916) 324-2641, at 450 N Street, Sacramento, CA 95814, e-mail Cary.Huxsoll@boe.ca.gov or MIC:82, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0082.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Mr. Rick Bennion, Regulations Coordinator, telephone (916) 445-2130, fax (916) 324-3984 , e-mail Richard.Bennion@boe.ca.gov or by mail at State Board of Equalization, Attn: Rick Bennion MIC:81, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0080.

ALTERNATIVES CONSIDERED

The Board must determine that no reasonable alternative considered by it or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored and strikeout version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed regulation are available on the Internet at the Board's Web site http://www.boe.ca.gov.

AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's Web site following its public hearing of the proposed regulation. It will also be available for public inspection at 450 N Street, Sacramento, California.

ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Mr. Bennion. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.

Sincerely,

Diane G. Olson

Diane G. Olson, Chief
Board Proceedings Division

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Enclosures

INITIAL STATEMENT OF REASONS
NON-CONTROLLING SUMMARY

Sales and Use Tax Regulations 1591, *Medicines and Medical Devices*

Specific Purpose

The purpose of the proposed amendments to California Code of Regulations, title 18, sections 1591, *Medicines and Medical Devices*, is to amend, subdivision (b)(2), to clarify that tax does not apply to the sale of *all* "permanently implanted articles" including an implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

Necessity

This regulation is necessary to provide clarification to taxpayers and staff regarding the taxation of implanted medical devices.

Factual Basis

On February 27, 2008, the Board of Equalization (Board) heard a sales and use tax appeals case regarding the sales of cochlear implant devices. At issue was whether sales of the external components of the ear implant device qualified for exemption from tax in the same manner as the permanently implanted internal components. The petitioner explained that the internal and external components of the ear implant device are effectively one device, with each component mutually dependent on the other to function. Together, the internal and external components of the ear implant device assist in the functioning of the ear, each necessary and integral to the ongoing function of the ear and, as such, both qualify as "medicines." The Board agreed with the petitioner and instructed staff to amend Regulation 1591 to clarify the matter.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances,

dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503.

For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIETARY SUPPLEMENTS AND ADJUNCTS. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the

substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Regulation History

Type of Regulation: Sales and Use Tax

Regulation: 1591

Title: 1591, Medicines and Medical Devices

Preparation: Lynda Cardwell
Legal Contact: Cary Huxsoll

Adoption of proposed amendments to clarify the application of tax to sales of interdependent external and internal components of permanently implanted devices.

History of Proposed Regulation:

February 3, 2008	Board approves amendment (Vote 5-0)
February 3, 2008	Public hearing
January 26, 2009	45-day public comment period ends
December 12, 2008	OAL publication date; 45-day public comment period begins; IP mailing
December 2, 2008	Notice to OAL
November 12, 2008	BTC Board Authorized Publication (vote 5-0)
September 22, 2008	Last day for IP to respond to Second Discussion Paper
September 9, 2008	Second Interested Parties (IP) meeting
August 1, 2008	Last day for IP to respond to Initial Discussion Paper
July 16, 2008	First Interested Parties (IP) meeting

Sponsor:	NA
Support:	NA
Oppose:	NA

Statement of Compliance

The State Board of Equalization, in process of adopting Sales and Use Tax Regulation 1591, Medicines and Medical Devices , did comply with the provision of Government Code section 11346.4(a)(1) through (4). A notice to interested parties was mailed on December 12, 2008, 53 days prior to the public hearing.

January 16, 2009

Richard E. Bennion
Regulations Coordinator
State Board of Equalization

BEFORE THE CALIFORNIA STATE BOARD OF EQUALIZATION

450 N Street, Room 121

Sacramento, California

REPORTER'S TRANSCRIPT

FEBRUARY 3, 2009

ITEM F2

PUBLIC HEARINGS

SALES AND USE TAX REGULATION 1591,

MEDICINES AND MEDICAL DEVICES

Reported by: Beverly D. Toms

No. CSR 1662

P R E S E N T

For the Board of Equalization:	Betty Yee Chair
	Judy Chu Vice-Chair
	Bill Leonard Member
	Michelle Steel Member
	Marcy Jo Mandel Appearing for John Chiang, State Controller (per Government Code Section 7.9)
	Diane Olson Chief, Board Proceedings Division
Board of Equalization Staff:	Robert Tucker Legal Department

---oOo---

Sacramento, California

February 3, 2009

---oOO---

MS. OLSON: The next item is F2, Sales and Use Tax Regulation 1591, Medicines and Medical Devices. It's a public hearing

MS. YEE: Okay.

Okay, Mr. Tucker.

MR. TUCKER: Good morning Madam Chairwoman and Members. My name is Robert Tucker on behalf of the Legal Department.

Staff is requesting that the Board adopt the proposed amendments to Regulation 1591. These amendments will clarify that all permanently implanted articles include the implant's interdependent internal and external components which operate together as one device in and on the person in whom the device is implanted. Including ear implants unless the device is excluded from the definition of medicines.

Thank you.

MS. YEE: Thank you. We have no speakers signed up for this item.

MR. LEONARD: Move adoption.

DR. CHU: Second.

MS. YEE: Second by -- excuse me, motion by Mr. Leonard, second by Dr. Chu to adopt the staff recommendation.

Without objection, such will be the order.

---oOo---

REPORTER'S CERTIFICATE

State of California)
) ss
County of Sacramento)

I, BEVERLY D. TOMS, Hearing Reporter for the California State Board of Equalization certify that on February 3, 2009 I recorded verbatim, in shorthand, to the best of my ability, the proceedings in the above-entitled hearing; that I transcribed the shorthand writing into typewriting; and that the preceding 3 pages constitute a complete and accurate transcription of the shorthand writing.

Dated: March 12, 2009.

_____

BEVERLY D. TOMS
Hearing Reporter

2009 MINUTES OF THE STATE BOARD OF EQUALIZATION

Tuesday, February 3, 2009

PUBLIC HEARINGS

Property Taxes - State Assessees' Presentations on Capitalization Rates and Other Factors Affecting Values

Ken Thompson, Principal Property Appraiser, State Assessed Properties Division, Property and Special Taxes Department, made introductory remarks regarding the state assessees' presentations on capitalization rates, other factors and procedures affecting 2009-10 property values of California public utilities, railroads and pipelines; and, private railroad car assessees' presentations on factors and procedures affecting 2009-10 taxable values of private railroad cars (Exhibit 2.1).

Speakers: Justin Hyland, Calpine Corporation
Peter W. Hladek, Thomson Property Tax Services
Fred Vance, Calpine Corporation
Peter W. Michaels, Law Offices of Peter Michaels

Mr. Leonard directed staff to include in the summaries the following information: give choices by providing a range or band in the analysis of the cap rate and not just hard numbers; reflect the entire appeals process so to have one document that includes both positions and their arguments; and, have a comparison band of companies that are regulated versus non regulated and should that be impossible due to lack of date, then it should be stated.

Ms. Yee directed staff to have early engagement with the assesses so the summaries are distributed timelier with all attachments.

Sales and Use Tax Regulation 1591, *Medicines and Medical Devices*

Robert Tucker, Tax Counsel, Business Taxes Division, Legal Department, made introductory remarks regarding the proposed amendments to clarify the application of tax to sales of interdependent external and internal components of permanently implanted devices (Exhibit 2.2).

Speakers were invited to address the Board, but there were none.

Action: Upon motion of Mr. Leonard, seconded by Dr. Chu and unanimously carried, Ms. Yee, Dr. Chu, Mr. Leonard, Ms. Steel and Ms. Mandel voting yes, the Board approved the proposed amendments.

LEGAL APPEALS MATTERS, CONSENT

With respect to the Legal Appeals Matters Consent Agenda, upon a single motion of Dr. Chu, seconded by Mr. Leonard and unanimously carried, Ms. Yee, Dr. Chu, Mr. Leonard, Ms. Steel and Ms. Mandel voting yes, the Board made the following orders:

STATE OF CALIFORNIA

ATE BOARD OF EQUALIZATION
N STREET, SACRAMENTO, CALIFORNIA
PO BOX 942879, SACRAMENTO, CALIFORNIA 94279-80
916-445-2130 • FAX 916-324-3984
www.boe.ca.gov

December 12, 2008

To Interested Parties:

Notice of Proposed Regulatory Action
by the
State Board of Equalization

Proposed to Adopt Regulation 1591, *Medicines and Medical Devices*

NOTICE IS HEREBY GIVEN

The State Board of Equalization (Board), pursuant to the authority vested in it by section 15606, subdivision (a), of the Government Code, proposes to amend Regulation 1591, *Medicines and Medical Devices*, in Title 18, Division 2, Chapter 4, Articles 19 and 20 of the California Code of Regulations, relating to regulatory changes to clarify that all "permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

"Permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines.

A public hearing on the proposed regulations will be held in Room 121, 450 N Street, Sacramento, at 9:30 a.m., or as soon thereafter as the matter may be heard, on Tuesday, February 3, 2009. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by February 3, 2009.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Revenue and Taxation Code (RTC) section 6369, interpreted and implemented by Regulation 1591, provides that sales of medicines furnished for the treatment of a human being are exempt from sales or use tax if they are sold or furnished under certain conditions, as described in subdivisions (a)(1) through (a)(6) of that section. The term "medicines" is defined by RTC

section 6369, subdivision (c), in part, to mean and include "bone screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body."

Regulation 1591, subdivision (b)(2), provides in part and with emphasis added:

"Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines...."

"Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants."

The proposed amendments would amend regulation 1591(b)(2) to clarify that tax does not apply to the sale of *all* "permanently implanted articles" including an implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendments do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5, subdivision (a)(8), the Board of Equalization makes an initial determination that the adoption of the amendments to Regulation 1591 will have no significant statewide adverse economic impact directly affecting business.

The adoption of the proposed amendments to these regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The amendments to the regulations as proposed will not be detrimental to California businesses in competing with businesses in other states.

The proposed regulations may affect small business.

COST IMPACT ON PRIVATE PERSON OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

FEDERAL REGULATIONS

Regulations 1591 and the proposed changes have no comparable federal regulations.

AUTHORITY

Section 7051, Revenue and Taxation Code.

REFERENCE

Section 6369, Revenue and Taxation Code.

CONTACT

Questions regarding the substance of the proposed regulation should be directed toMr. Cary Huxsoll (916) 324-2641, at 450 N Street, Sacramento, CA 95814, e-mail Cary.Huxsoll@boe.ca.gov or MIC:82, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0082.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Mr. Rick Bennion, Regulations Coordinator, telephone (916) 445-2130, fax (916) 324-3984 , e-mail Richard.Bennion@boe.ca.gov or by mail at State Board of Equalization, Attn: Rick Bennion MIC:81, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0080.

ALTERNATIVES CONSIDERED

The Board must determine that no reasonable alternative considered by it or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored and strikeout version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed regulation are available on the Internet at the Board's Web site http://www.boe.ca.gov.

AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's Web site following its public hearing of the proposed regulation. It will also be available for public inspection at 450 N Street, Sacramento, California.

ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Mr. Bennion. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.

Sincerely,

Diane G. Olson

Diane G. Olson, Chief
Board Proceedings Division

DGO:reb

Enclosures

STATE BOARD OF EQUALIZATION

BOARD APPROVED
At the February 3, 2009 Board Meeting
Diane G. Olson
Diane G. Olson, Chief
Board Proceedings Division

INITIAL STATEMENT OF REASONS
NON-CONTROLLING SUMMARY

Sales and Use Tax Regulations 1591, *Medicines and Medical Devices*

Specific Purpose

The purpose of the proposed amendments to California Code of Regulations, title 18, sections 1591, *Medicines and Medical Devices*, is to amend, subdivision (b)(2), to clarify that tax does not apply to the sale of *all* "permanently implanted articles" including an implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

Necessity

This regulation is necessary to provide clarification to taxpayers and staff regarding the taxation of implanted medical devices.

Factual Basis

On February 27, 2008, the Board of Equalization (Board) heard a sales and use tax appeals case regarding the sales of cochlear implant devices. At issue was whether sales of the external components of the ear implant device qualified for exemption from tax in the same manner as the permanently implanted internal components. The petitioner explained that the internal and external components of the ear implant device are effectively one device, with each component mutually dependent on the other to function. Together, the internal and external components of the ear implant device assist in the functioning of the ear, each necessary and integral to the ongoing function of the ear and, as such, both qualify as "medicines." The Board agreed with the petitioner and instructed staff to amend Regulation 1591 to clarify the matter.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances,

dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503.

For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIETARY SUPPLEMENTS AND ADJUNCTS. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the

substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Regulation History

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Regulation: 1591

Title: 1591, Medicines and Medical Devices

Preparation: Lynda Cardwell
Legal Contact: Cary Huxsoll

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February 3, 2008	Public hearing
January 26, 2009	45-day public comment period ends
December 12, 2008	OAL publication date; 45-day public comment period begins; IP mailing
December 2, 2008	Notice to OAL
November 12, 2008	BTC Board Authorized Publication (vote 5-0)
September 22, 2008	Last day for IP to respond to Second Discussion Paper
September 9, 2008	Second Interested Parties (IP) meeting
August 1, 2008	Last day for IP to respond to Initial Discussion Paper
July 16, 2008	First Interested Parties (IP) meeting

Sponsor:	NA
Support:	NA
Oppose:	NA